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No. 09-1022

In the Supreme Court of the United States

BAYER SCHERING PHARMA AG and
BAYER HEALTHCARE PHARMACEUTICALS INC.,
Petitioners,

v.

BARR LABORATORIES, INC.,
Respondent.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR RESPONDENT IN OPPOSITION

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QUESTION PRESENTED

Whether the Federal Circuit erred by holding certain patent claims obvious, and therefore invalid, based on well-supported findings of fact establishing that the claimed invention was one of a finite number of identified, predictable solutions a person of ordinary skill in the art could undertake with a reasonable expectation of success.

CORPORATE DISCLOSURE STATEMENT

Pursuant to Rule 29.6, respondent Barr Laboratories, Inc. states that its parent companies are as follows: Barr Pharmaceuticals, LLC; Teva Pharmaceuticals USA, Inc.; Orvet UK; Teva Pharmaceutical Holdings Cooperatieve U.A.; Ivax LLC; Teva Pharmaceuticals Europe B.V.; and Teva Pharmaceutical Industries Ltd.

Teva Pharmaceuticals Industries Ltd. is the only publicly-traded parent company of Barr Laboratories, Inc., and no other publicly-traded company directly or indirectly owns more than 10% of its stock.

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INTRODUCTION

This case simply does not present the question posed by the petition. Petitioners (together, "Bayer") ask this Court to consider whether an invention can be deemed obvious "even though it remained necessary to conduct further experimentation, the results of which were unpredictable." Pet. i, 10. But this is not the holding of the decision below. Bayer took a medication everyone already knew would work—an oral contraceptive based on the drug drospirenone—and put it in the same "normal," immediate-release tablet that was used at the time for every other oral contraceptive pill on the market. Applying settled principles of law in light of the factual findings and credibility determinations of the judge at trial, the Federal Circuit properly concluded that this supposed "innovation"—delivering a known drug, for a known purpose, in the usual way—was not innovative at all.

Attempting to manufacture a legal issue fit for this Court's review, the petition depends on a pair of mischaracterizations.

First and foremost, Bayer's petition depends on an incomplete and misleading presentation of the factual record. Any assessment of obviousness under 35 U.S.C. §103 must begin with a determination of the underlying facts, including the scope and content of the prior art, the differences between the prior art and the claims at issue, and the level of ordinary skill in the art. And these determinations are made given the knowledge available *at the time the patent is filed*, 35 U.S.C. §103(a), which in this case is August 1999. Bayer's petition takes the facts as Bayer would like them to be, not as the district court found them based on credibility and factual determinations made after a trial on the merits.

Indeed, both the petition and the dissent below focus on testimony by a Bayer researcher that he made an informed judgment *in 1983* that this ordinary formulation would fail, only to be "surprised" in 1988 to discover that it succeeded. The district court found this story not credible and not probative of obviousness. Instead, assessing the invention from the point of view of a person of ordinary skill in the art at the time of the patent application *in 1999*, the court concluded that the claimed formulation was among "a finite number of identified, predictable solutions" that a skilled formulator would have pursued with a reasonable expectation of success. Pet. App. 98a (quoting *KSR Int'l Co.* v. *Teleflex Inc.*, 550 U.S. 398, 421 (2007)). The Federal Circuit agreed. *Id.* at 15a. Ignoring the prior art on which the courts below based their conclusions, Bayer's petition depends on a factual story rejected by the courts below and thus raises—at best—factual disputes not suitable for this Court's review. It should be denied on that basis.

Second, the petition mischaracterizes the rule of law applied below. Bayer contends the Federal Circuit jettisoned predictability from the obviousness standard, but this is simply not so. A claimed invention is obvious if it is one of a finite number of identified predictable solutions a person of ordinary skill could undertake with a reasonable expectation of success. This is the standard set by *KSR*, and it is the standard expressly applied by the decision below. See Pet. App. 8a-10a, 14a-15a. The Federal Circuit has neither unsettled the law nor otherwise "endorse[d] a lower 'obviousness' standard than the one required by Congress and this Court." Pet. 3.

Independent of Bayer's contention that the decision below departs from *KSR*, Bayer's other arguments for certiorari have little value—except perhaps

to distract from a factual record that makes the decision below legally uninteresting. See *KSR*, 550 U.S. at 417 (observing that a relatively easy case of obviousness is posed where the claimed subject matter involves "the mere application of a known technique to a piece of prior art ready for the improvement"). Bayer argues that there is both a circuit split and a conflict within the Federal Circuit over the legal standard for obviousness, but these arguments depend almost entirely on cases that *pre-date KSR*. See Pet. 20-25. Nor is the PTO, which already has a revision to its obviousness guidelines in the works, in need of additional guidance from this Court at this time. The petition should be denied.

STATEMENT

1. The '531 patent claims a composition of 2 to 4 mg of micronized drospirenone, 0.01 mg to 0.05 mg of 17α-ethinylestradiol, and one or more pharmaceutically acceptable carriers, in an immediate-release tablet, effective as an oral contraceptive in a human female. Pet. App. 6a-7a, 44a. Bayer first claimed a combination of drospirenone and ethinylestradiol in U.S. Patent No. 4,129,564, which issued in 1978. By the time Bayer filed for the '531 patent in 1999, it was well known that the combination of these ingredients, in these dosages, would be an effective oral contraceptive. Pet. App. 7a, 93a. What was supposedly "new" in this '531 patent was the particular "formulation" used—namely, "micronizing" the ingredients (reducing particle size to enhance absorption) and delivering them via an "immediate-release" tablet. *Id.* at 7a, 22a.

By 1999, however, at least five pieces of prior art—none of which is mentioned in the petition—expressly taught "that drospirenone in combination with ethinylestradiol would be formulated by conven-

tional methods as an effective oral contraceptive." Pet. App. 93a. For oral contraceptives (and indeed, pharmaceuticals generally), nothing is so "conventional" as the formulation claimed in Bayer's patent. Indeed, that formulation had been used in *every* commercially available oral contraceptive since the 1970s. The "invention" at issue here is thus nothing more than the application of conventional techniques to a known set of ingredients to make what Bayer scientists and others in the field generally referred to as a "normal" tablet. Pet. App. 6a, 38a-39a.

2. For the skilled formulator in 1999, this conventional formulation for drospirenone would have been a predictable success.

Micronization is a common technique for dealing with poorly water soluble drugs to improve dissolution, absorption, and bioavailability. Pet. App. 2a-3a. *All* of the formulation experts, including Bayer's, testified that a formulator's first step with drospirenone would have been to micronize the drug. *Id.* at 12a, 72a. The prior art reflects this consensus, teaching that micronization may be used even if a drug is acid-sensitive. See *id.* at 70a-72a. Bayer makes no serious argument to the contrary.

An oral contraceptive tablet containing micronized drospirenone could have been formulated in only two ways—normal (immediate-release) or enteric-coated (delayed-release). Bayer raised no other possible formulations, and there were none. An enteric coating, which prevents the tablet from dissolving until it reaches the intestines, is a second-best alternative to a normal formulation because it costs more, is more complicated, and creates variability problems. It is used as a last resort for drugs that "isomerize" (degrade into inactive isomers) faster than they can be absorbed by the body. Pet. App. 3a-4a, 25a, 72a-76a.

A trilogy of studies identified by the courts below as "Krause I, II, and III" taught that spirorenone—a drug closely related to drospirenone—isomerizes under certain conditions in vitro (in a test tube) but does *not* isomerize in vivo (in the body). See Pet. App. 13a-14a, 76a-83a. The courts below found that a person of ordinary skill would have relied on Krause and recognized that *drospirenone does not need an enteric coating* because it absorbs in the body, even though it breaks down into inactive isomers in a test tube. That is, "drospirenone, like spirorenone, may absorb in vivo, but isomerize in vitro." See *id.* at 14a, 83a.

3. Bayer's account of the facts (Pet. 4-7) does not include Krause, or, indeed, most of the art available to a skilled formulator in 1999. Instead, Bayer's "novelty" argument depends primarily on evidence of its own story of working with drospirenone in the 1980s. Specifically, Bayer points to 1983, when its researcher Dr. Tack recommended using an enteric-coated tablet for drospirenone—a recommendation that drove Bayer's development efforts for several years, until Dr. Tack was "surprised" to discover (supposedly by accident) that enteric coating was not necessary after all. See Pet. App. 4a-6a, 35a-39a. According to Bayer, Dr. Tack's recommendation in 1983 and his "surprise" several years later demonstrate the novelty of the formulation.

The evidence at trial, however, told a different story: Inexperienced[1] and without the benefit of much

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[1] At the time, Dr. Tack was in his first months on the job as a bench scientist in Bayer's Galenics (Formulation) Department. Before joining that department, Dr. Tack did not have any formulation experience with drospirenone and had not conducted any other significant formulation work at Bayer. He had graduated in 1978 and spent the next several years working in a marketing department. See Pet. App. 32a-33a, 53a-54a.

of the art available in 1999, Dr. Tack recommended enteric coating by mistake, based on an in vitro test and an unreliable mathematical model. Sitting as finder of fact, the district court concluded that Dr. Tack's account lacked credibility and that his 1983 mistake was not probative of novelty in 1999. Pet. App. 51a-55a.

As the district court recognized, a skilled formulator in 1999 would have known that even if a drug is "acid-sensitive" under extreme conditions in a test tube, enteric coating is necessary *only* if the drug becomes inactive in the stomach faster than it is absorbed. See Pet. App. 65a-66a, 69a-70a. To be sure, there were general statements in general treatises that acid-sensitive drugs could be enteric coated, but a person of ordinary skill would have understood that general statements in general treatises are not universally applicable. See *id.* at 74a-76a. Digoxin, for example, is even more acid-sensitive than drospirenone, and yet it does not require enteric coating. At trial, Bayer did not identify a single acid-sensitive drug that had to be enteric-coated.[2]

4. For these reasons, following §103(a) and assessing the prior art from the point of view of the person of ordinary skill in 1999, the district court held that the asserted claims of the '531 patent were obvi-

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[2] Because Bayer argued teaching-away (see Pet. App. 14a-15a), the courts below also considered the importance a formulator would place, in this particular context, on a correlation between in vitro (test tube) and in vivo (body) results. Based on Krause and other art ignored by the petition, a person of ordinary skill in the art would *not* have viewed a single extreme in vitro result as predictive of what would happen to drospirenone in vivo. See, *e.g.*, *id.* at 11a ("in vitro tests only have significance if they can be related to in vivo results"); *id.* at 66a (for immediate-release tablets in particular, in vitro/in vivo correlations are rare).

ous and therefore invalid. Pet. App. 20a-99a.[3] On appeal—based on the district court's well-founded factual findings and a straightforward application of *KSR*—the Federal Circuit affirmed. *Id.* at 1a-16a. Bayer's petition for rehearing and rehearing en banc was denied without comment. *Id.* at 129a.

REASONS FOR DENYING THE PETITION

The petition should be denied for two simple reasons.

First, it depends on factual assumptions that are inappropriate on this record—and thus, effectively takes issue with the lower courts' reading of the facts. When the factual findings below are properly credited, the issue posed by the petition simply evaporates.

Second, the petition is premised on a mischaracterization of the rule of law applied by the Federal Circuit. An invention is obvious and therefore invalid where it is one of a finite number of identified, predictable solutions a person of ordinary skill in the art could undertake with a reasonable expectation of success. This is the standard set by this Court just three

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[3] After the district court entered judgment, Bayer and Barr reached an agreement giving Barr the right to market a generic form of Bayer's oral contraceptive product, Yasmin®. Among other provisions, the agreement includes a differential royalty rate: Barr pays more money if it ultimately loses this case, less if it wins. Watson Laboratories, Inc. is not a party to this case, but it too would like to market a generic form of Yasmin®. Attempting to defend the favorable judgment obtained by Barr, Watson sought leave to intervene in the Federal Circuit and filed a motion to dismiss Bayer's appeal, arguing that the parties' agreement had destroyed federal jurisdiction by resolving the controversy between Barr and Bayer. The parties briefed the issue thoroughly, and Watson's motion was denied. See Order, No. 2008-1282 (Fed. Cir. Oct. 3, 2008) (Mayer, J.).

years ago in *KSR*; it is the standard Bayer admits to having advocated in the court below (Pet. 21 n.1); and it is the standard expressly and correctly applied by the Federal Circuit. Because the decision below does not unsettle the law, the petition should be denied.

I. Bayer's Complaints Are Ultimately Factual.

In *KSR*, this Court rejected an obviousness analysis that had grown overly rigid. The Court warned against "[g]ranting patent protection to advances that would occur in the ordinary course without real innovation." 550 U.S. at 419. The Court also reaffirmed "the need for caution in granting a patent based on the combination of elements found in the prior art" (*id.* at 415), instructing,

> When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under § 103.

Id. at 421. In this litigation, both parties and both courts below agreed that this is the standard that governs this case. Where the parties parted company, however, was with respect to the relevant facts. As discussed below, those factual disputes remain the focus of the petition—which alone is sufficient basis for this Court to deny it.

A. Bayer ignores the prior art on which the Federal Circuit primarily based its finding that the claimed invention was a predictable success.

Under the *KSR* standard, one of the central issues at the trial in this case was just what a person of ordinary skill would make of the prior art, and particularly of the studies known as the "Krause series." This was also one of the central issues on appeal—including in Bayer's petition for rehearing en banc. And yet this Court will search Bayer's petition in vain for any express mention of Krause. Instead, Bayer includes only a few cryptic references to "a drug related to drospirenone." See Pet. 8, 18. That drug is spirorenone, and Krause taught that this closely related drug degrades into inactive isomers under certain conditions in a test tube, but *not* in the stomach. To the contrary, in micronized form, when orally ingested and exposed directly to gastric acid, spirorenone absorbed. Pet. App. 13a-14a, 83a.

Like the district court, the Federal Circuit carefully considered Krause's importance to the skilled formulator of drospirenone. Both courts recognized that Krause undertook to make the very same formulation decision at issue here, for a closely related drug, and found no need for enteric coating: "The Krause series tested the bioavailability of spirorenone in vivo in humans and monkeys to determine whether there was need to develop a 'pharmaceutical formulation resistant to gastric juice'"—*i.e.*, an enteric coating. Pet. App. 13a. Specifically, Krause gave his subjects uncoated (and in Krause II, micronized) doses of spirorenone and then tested their blood to determine whether exposing the spirorenone directly to stomach acid caused the drug to break down into an inactive isomer. *Id.* at 77a-80a. If there had been

isomerization, an enteric coating might have been necessary. But in fact, "[t]he studies each found no spirorenone isomers in the subjects' blood streams, and concluded that spirorenone is absorbed before it isomerizes." *Id.* at 13a.

The Federal Circuit also reviewed the district court's conclusion that spirorenone and drospirenone are closely related, and found it amply supported: drospirenone and spirorenone "are both (1) acid-sensitive at similar rates, (2) steroids having the same pharmacological properties, (3) derivatives of the same drug, (4) of the same chemical composition except for one bond, and (5) from the same family of substances." Pet. App. 14a. For these reasons, "a person of ordinary skill would find the drugs closely related, and would therefore access [the Krause] studies when formulating drospirenone. *He would be led to believe that drospirenone, like spirorenone, may absorb in vivo, but isomerize in vitro.*" *Ibid.* (emphasis added); see also *id.* at 80a-81a.

Accordingly, the Federal Circuit agreed with the district court that Krause would have given the person of ordinary skill in the art a reasonable expectation that unprotected micronized drospirenone would be effective. Rejecting Bayer's arguments about Krause's supposed insignificance, the court below explained,

> [T]he Krause series prior art is not an anticipatory reference. It can be used to show that a drug formulator having ordinary skill had a viable known option to consider with micronized, unprotected drosperinone, and a reasonable expectation that drosperinone would perform similarly (even if not identically) to the spirorenone in the Krause series. *See* [*In re O'Farrell*, 853 F.2d

> 894, 903-904 (Fed. Cir. 1988)] ("Obviousness does not require absolute predictability of success ... all that is required is *a reasonable expectation of success.*").

Pet. App.14a (emphasis added); see also *id.* at 80a-81a, 83a-84a.

Unsurprisingly, Bayer's appellate challenge to these findings failed because the "contention that the prior art deals with a problem that is not directly analogous to the problem facing the inventors . . . is a factual question." *Commonwealth Scientific & Indus. Research Org.* v. *Buffalo Tech. (USA), Inc.*, 542 F.3d 1363, 1375 (Fed. Cir. 2008). The Federal Circuit rejected Bayer's clear-error arguments and agreed with the district court that Krause would have led the person of ordinary skill in the art to "delivery of micronized drospirenone by a normal pill following the spirorenone analogy in the Krause series." Pet. App. 15a. And because formulating drospirenone in this way "led to the result anticipated by the Krause series, the invention would have been obvious." *Ibid.* Bayer seeks review of the Federal Circuit's ultimate legal conclusion of obviousness, but that conclusion is plainly correct in light of the findings of fact related to Krause.

B. Bayer's reliance on its development story is contrary to the findings of the courts below.

Ignoring the prior art available to guide the person of ordinary skill in 1999, the petition instead focuses on Bayer's story of its much earlier internal experiments with drospirenone. Specifically, Bayer relies on the testimony of its own Dr. Tack, who claimed at trial that he recommended enteric coating for the drug in 1983, based on his own understanding

of the drug's characteristics, and was surprised to discover several years later that enteric coating was not required after all. Putting aside whether this evidence was legally relevant in the first place,[4] the district court, sitting as finder of fact, found Dr. Tack himself less than credible and the internal-development evidence as a whole to be unhelpful in determining what a skilled formulator would have done with drospirenone ten to fifteen years later, at the time the patent application was filed. Pet. App. 51a-55a.

Most notably, the district court questioned whether the young Dr. Tack was a match for the hypothetical person of ordinary skill in the art. Pet. App. 53a-54a. Formulating drospirenone was Dr. Tack's first major assignment following school, and Dr. Tack undertook that project having just spent three years in a marketing department; "it is fair to conclude that his skills as a formulator probably regressed or slipped during that time period." *Id.* at 54a. The court did not err in rejecting the expectations of this single, real inventor with his real shortcomings, and evaluating instead the "imaginary being . . . created by Congress to provide a standard of patentability." *Kimberly-Clark Corp.* v. *Johnson & Johnson*, 745 F.2d 1437, 1454 (Fed. Cir. 1984) (emphasis omitted) ("courts never have judged patentability by what the real inventor/applicant/patentee could or would do . . . the courts have always applied a standard based on an imaginary worker of their own devising whom they have equated with the inventor").

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[4] See *KSR*, 550 U.S. at 420 ("The question is not whether the combination was obvious to the patentee but whether the combination was obvious to a person with ordinary skill in the art.").

The district court also found that Dr. Tack was led to the wrong result in 1983 by using a flawed mathematical "compartment model" of his own creation. The court explained, "Dr. Tack did not provide any citation to the prior art which confirms the trustworthiness of the model—that is, whether it was a generally accepted compartment model used in the field of pharmacology." Pet. App. 52a-53a. In fact, the compartment model has never been accepted in the field and would *not* have been used by a person of ordinary skill in 1999. It was created and used by the young Dr. Tack in 1983—and it led him to the wrong conclusion. The district court properly found little value in a flawed analysis that the person of ordinary skill in the art simply would not have performed.

In addition, the district court found that the 10-year gap between Dr. Tack's work with drospirenone and the filing date of the '531 patent diminished the correlation between Tack's perception of the art and that of the person of ordinary skill in 1999. Pet. App. 52a. In concluding that there were significant advances in pharmacology between 1988 and 1999 (*ibid.*), the court correctly acknowledged that obviousness is determined given the knowledge available at the time the patent is filed, as opposed to the time when Dr. Tack was carrying out his clinical studies. 35 U.S.C. §103(a).

By setting the clock at 1983, Bayer substantially overstates the supposed innovation here. In 1983, says Bayer, success in developing drospirenone as an oral contraceptive "was far from guaranteed." Pet 4. By 1999, however, multiple pieces of prior art—none of which is addressed in Bayer's petition—taught that drospirenone could be used successfully as an oral contraceptive. See Pet. App. 91a-93a. For example, two preexisting patents taught that a drospirenone

oral contraceptive should be formulated in a manner "*completely analogously as it is already known for usual oral contraceptives*," and another reference similarly taught that the combination should be "admixed together" using "*conventional methodology*." *Id.* at 93a (emphasis added). Bayer suggests that failure was an option (Pet. 20), but the art taught otherwise.

In fact, the '531 patent was plainly an attempt by Bayer to extend its drospirenone monopoly past the expiration of Bayer's 1978 patent on the combination of drospirenone and ethinylestradiol. The '531 patent claimed a known combination of ingredients, in known dosages, for a known use, using standard formulation techniques. Calling that "invention" what it was—obvious—does not decrease the incentives for innovation. "[A]dvances, once part of our shared knowledge, define a new threshold from which innovation starts once more. And as progress beginning from higher levels of achievement is expected in the normal course, the results of ordinary innovation are not the subject of exclusive rights under the patent laws." *KSR*, 550 U.S. at 427; see also *Great Atlantic & Pacific Tea Co.* v. *Supermarket Equip. Corp.*, 340 U.S. 147, 152 (1950) ("The function of a patent is to add to the sum of useful knowledge. Patents cannot be sustained when, on the contrary, their effect is to subtract from former resources freely available to skilled artisans."). Bayer enjoyed a three-decade patent monopoly over oral contraceptives containing drospirenone. Bayer has been amply rewarded already. Certiorari should be denied.

II. The Petition Mischaracterizes The Rule Of Law Applied By The Federal Circuit.

The petition also should be denied because there is no true dispute about the obviousness standard. Based on the district court's well-supported factual findings regarding the scope and content of the prior art, the Federal Circuit correctly held that it would have been obvious for a person of ordinary skill to try a micronized, immediate-release formulation of drospirenone—and that such a formulation would have been reasonably expected to work. The Federal Circuit did not stray from *KSR* or otherwise disregard predictability, and thus this Court's intervention is not warranted.

A. Bayer misstates the holding of the decision below.

1. Attempting to clothe its factual defeat in legal garb, Bayer first argues that the Federal Circuit "transformed the predictability inquiry into a question of whether the potential solutions were 'particular'" through its discussion of *In re O'Farrell*, 853 F.2d 894 (Fed. Cir. 1988). See Pet. 17-18 (discussing Pet. App. 9a-10a, 15a). The Federal Circuit actually did no such thing.

In *KSR*, this Court rejected a rule "that a patent claim cannot be proved obvious merely by showing that the combination was 'obvious to try,'" holding instead that, when known options lead to "anticipated success," "the fact that a combination was obvious to try might show that it was obvious under § 103." 550 U.S. at 421. In the decision below, the Federal Circuit explained that *O'Farrell* had similarly "observed that most inventions that are obvious were also obvious to try, but found two classes where that rule of thumb did not obtain." Pet. App. 9a-10a. First, an invention

is not obvious "where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful," which, the Federal Circuit noted, was "another way to express the *KSR* prong requiring the field of search to be among a 'finite number of identified' solutions." *Id.* at 10a. Second, an invention also is not obvious where the art points only to a seemingly "promising field of experimentation" with "only general guidance as to the particular form of the claimed invention or how to achieve it," which the Federal Circuit noted expresses the "same idea as the *KSR* requirement that the identified solutions be 'predictable.'" *Ibid.* In both instances, the Federal Circuit correctly stated the *KSR* standard as requiring a finite number of identified solutions and predictability. See also *O'Farrell*, 853 F.2d at 901-03 (analyzing extent to which the key prior art "predicted" success).

The Federal Circuit did not transform the predictability inquiry into a question of whether the "potential solutions were 'particular.'" Pet. 18. Rather, the court specifically stated—before, during, and after its discussion of *O'Farrell*—that it was applying the *KSR* predictability standard: A claimed invention may be obvious, the Federal Circuit explained, where it is simply the result of identifying "a finite number of identified, *predictable* solutions" and "pursu[ing] the *known options* . . . to the anticipated success." Pet. App. 9a (quoting *KSR*) (emphasis added). Here, the court found that the normal micronized tablet was a known and predictably successful option: "The prior art would have funneled the formulator toward these two options"—that is, to two "identified, predictable solutions"—and not to a field with limitless "possibilities" or to a "general approach or area of exploration." *Id.* at 15a. Because the normal micronized dro-

spirenone tablet was a "predictable solution" with a "reasonable expectation" that it would work, and its use in fact led to the "anticipated success," the invention was obvious. *Id.* at 9a, 14a, 15a.

2. Bayer also snips the phrase "viable options" from the decision below and claims that it represents a new and different standard. Pet. 17-19. This too is wrong. Considered in context, the reference to "viable options" refers to the fact that the normal tablet was one of a finite number of known, available options for which there was a reasonable expectation of success. Pet. App. 14a. Without any support, Bayer and the dissenting judge below object that "viability" implies "guesswork" or "dumb luck," as opposed to "a reasonable degree of predictability." *Id.* at 18a; Pet. 18-19. Not so. According to Merriam-Webster's Collegiate Dictionary (11th ed. 2003), one definition of "viable" is "having a reasonable chance of succeeding," as in "a viable candidate." And in any event, the passing reference to "viable" options does not change the obviousness analysis applied below. The majority below sought and found the very predictability on which the dissent insisted.

Bayer goes on to argue that viable options giving rise to a reasonable expectation of success is not the same thing as a predictable solution that anticipates success. Pet. 18. But as Bayer notes only later in its petition, and then in a footnote, *Bayer itself urged the "reasonable expectation of success" standard on the Federal Circuit.* *Id.* at 21 n.1. To be sure, Bayer does not like the result, but that is a complaint with the factual conclusions of the two courts below, not the legal standard applied. And in any event, as explained in more detail below, the Federal Circuit correctly concluded that predictability does not require absolute certainty: an invention is obvious to try and

invalid if success by a person of ordinary skill in the art would be reasonably anticipated. Pet. App. 14a.

3. In making these arguments, the petition's central discussion of the Federal Circuit's supposed legal error (at 17-19) parses the case law and the decisions below as if they were statutes. By choosing, comparing, and contrasting individual words from these decisions, the petition constructs a legal-standards argument that falls far short of doing justice to a highly fact-intensive area of the law. In fact, the Federal Circuit has warned in this very context that it does not use precedent as Bayer fears: "Obviousness is a complicated subject requiring sophisticated analysis, and no single case lays out all facets of the legal test. [There is] danger inherent in focusing on isolated dicta rather than gleaning the law of a particular area from careful reading of the full text of a group of related precedents for all they say that is dispositive and for what they hold." *Pfizer, Inc.* v. *Apotex, Inc.*, 480 F.3d 1348, 1366 (Fed. Cir. 2007) (quoting *DyStar Textilfarben GmbH* v. *C.H. Patrick Co.*, 464 F.3d 1356, 1367 (Fed. Cir. 2006)).

Bayer's presentation of the district court's decision is similarly contrived. For example, ignoring the district court's final conclusions based on its review of the entirety of the prior art available in 1999, Bayer takes issue with a preliminary conclusion—that "[t]he person of ordinary skill in the art would not rule out formulating a micronized drospirenone without enteric coating." Pet. App. 76a (quoted in Pet. at 7, 19). But it is simply not true that "[a]ll the district court could conclude" was that the skilled person "would not rule out" the claimed formulation. Pet. 19 (emphasis omitted). Instead, the court expressly stated that this and other preliminary conclusions "must be considered in light of" the more directly ap-

plicable references in the prior art. Pet. App. 76a. After considering those other references, the court went on to conclude that "micronization of drospirenone is consistent with the prior art and is obvious"; "the person of ordinary skill in the art would be led to an immediate release tablet"; and "[t]ogether, the prior art recognizes that drospirenone does not need an enteric coat." *Id.* at 96a-97a. Bayer does not grapple with these conclusions, and certiorari should not be granted based on a pretense that they do not exist. The decisions below are sound; it is the petition that is skipping steps.

B. Predictability does not mean certainty.

To the extent Bayer argues that patentability depends on the possibility the claimed option "might fail" (Pet. 20), this is not the law. A solution can be "perfectly plain," "immediately recognize[able]," or "suggested immediately and without effort" (*id.* at 18-19, citations omitted), and yet still need confirmation. Although it now disapproves of the "reasonable expectation of success" formulation (see, *e.g.*, *id.* at 10, 17-18, 24), Bayer admits that it urged the court below to evaluate obviousness in those very terms (*id.* at 21 n.1)—which are "the familiar terms of [the Federal Circuit's] longstanding case law." *In re Kubin*, 561 F.3d 1351, 1360 (Fed. Cir. 2009). Predictability is not certainty; it is a reasonable expectation of success. Pet. App. 14a.

KSR says as much: When there are a finite number of predictable solutions for solving a given design problem, "a person of ordinary skill has good reason *to pursue* the known options within his or her technical grasp. *If* this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." 550 U.S. at 421 (emphasis added).

And Bayer's own citations further make the point. In *Dow Chemical Co.* v. *Halliburton Oil Well Cementing Co.*, 324 U.S. 320 (1945), for example, the Court held that it was not innovative to use certain chemicals with well-known attributes in the field of oil-well drilling. See Pet. 15. The Court reached this conclusion notwithstanding the fact that the claimed use apparently had never been tried before—and thus the expectation of success still had to be confirmed. See 324 U.S. at 328. Indeed, the Court rejected the notion that "[h]e who is merely the first to utilize the existing fund of public knowledge for new and obvious purposes" thereby earns a patent. *Ibid.*

Conversely, in *Eibel Process Co.* v. *Minnesota & Ontario Paper Co.*, 261 U.S. 45 (1923), the Court upheld the patent because "there [was] no means, short of actual experiment[ation], to enable one to anticipate [the] results." *Id.* at 62 (quoted at Pet. 14). The instant case, by contrast, presented precisely the opposite situation: "Because the selection of micronized drospirenone in a normal pill led to the result anticipated by the Krause series, the invention would have been obvious." Pet. App. 15a.

In short, if success is predictable, the need for confirmation does not make a claim patentable. The whole point of *KSR* is that an invention is not innovative merely because the predictably successful option had yet to be tried. Sometimes "obvious *to try*" is obvious enough.

C. There is no larger problem in the Federal Circuit that counsels in favor of granting certiorari in this case.

1. Bayer discusses three cases to support the proposition that the decision below "is by no means the only Federal Circuit decision that has erroneously

eschewed this Court's predictability test." Pet. 20-21. For the reasons already given, the premise of the argument fails: the Federal Circuit below gave "predictability" its due.

In addition, the cases to which Bayer objects were all decided *before KSR*. It is difficult to "eschew" a standard that does not yet exist; pre-*KSR* cases are not pertinent to whether *KSR* was properly applied in this case. Moreover, the fact that these decisions discuss competing evidence—which is Bayer's hook for proposing that they were wrongly decided—does not suggest legal error so much as even-handedness and care in resolving fact-intensive cases. None of the cases Bayer discusses demonstrates any uncertainty in the law requiring this Court's review.[5]

First, Bayer argues that the Federal Circuit erred in *Pfizer, Inc.* v. *Apotex, Inc.*, 480 F.3d 1348 (Fed. Cir. 2007), by holding the invention obvious despite the trial court's finding that "it was *generally unpredictable* as to whether a particular salt would form and what its exact properties would be." *Id.* at 1364 (quoted, with added emphasis, in Pet. 20). In briefing below, however, Bayer offered a very different assessment of this case: Bayer highlighted the *Pfizer* court's statement "that its holding is based on the particularized facts of this case," and Bayer correctly pointed out that the court had "conclude[d] that the prior art predicted the results." Bayer Reply Br. at 28 (internal quotation marks and citations omitted).

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[5] Bayer also cites with disapproval the Federal Circuit's decision in *Pharmastem Therapeutics, Inc.* v. *Viacell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007), a case lost by the patentee. Contrary to what the petition would have the Court infer, however, the case was properly decided. See *id.* at 1363-64 (explaining that "the inventors merely used routine research methods to prove what was already believed to be the case").

Indeed, the Federal Circuit in *Pfizer* took pains to emphasize both those points. The court disagreed with an "unpredictability" conclusion reached by the district court because patentability cannot be based on the simple need to verify that which is reasonably expected to be true. 480 F.3d at 1364. And the court ultimately concluded, "*on the particularized facts of this case*, consideration of the 'routine testing' performed by Pfizer is appropriate because the prior art provided not only the means of creating acid addition salts *but also predicted the results* . . . ." *Id.* at 1367 (second emphasis added). Compare Pet. 24 (noting importance of distinguishing "between predictability in research *methods* and predictability in *results*").

Second, Bayer points to *In re Longi*, 759 F.2d 887 (Fed. Cir. 1985), where, according to Bayer, the court "invalidated a patent despite finding that the claimed compound's desirable functionality was 'not . . . predictable.'" Pet. 20 (quotation drawn from 759 F.2d at 897). Bayer's statement is wrong. *Longi* does not say that the "desirable functionality" was unpredictable; it says "*the exact magnitude*" of the desired effect "might not be predictable." See 759 F.3d at 896-97 (emphasis added). The PTO had rejected certain claims based on the rule that no one may obtain a second patent for an obvious modification of the same invention. See *id.* at 892. In the passage to which Bayer refers, the court is discussing a declaration submitted by the applicant, explaining that the Board correctly concluded that this declaration did not "provide the unexpected results necessary to rebut the prima facie case of obviousness." *Id.* at 896-97. Bayer pulls the two words, "not . . . predictable," out of context.

Third, Bayer points to *Verlander* v. *Garner*, 348 F.3d 1359 (Fed. Cir. 2003), where the court invali-

dated a patent for an invention that "was expensive, technically challenging, and laborious." Pet. 20-21 (quoting 348 F.3d at 1377). Bayer's critique of *Verlander* is a non sequitur. Difficulty and novelty are not the same thing; many human endeavors are extraordinarily hard, but that does not mean the end result is unpredictable. That was the Board's conclusion in *Verlander*: the method claimed was a difficult way to produce a particular protein, but it was also an obvious way, in no small part because *it had already worked as of the critical date* to produce proteins with similar characteristics. See 348 F.3d at 1377. The Board's finding of "obviousness" was tied to these specific facts, and the Federal Circuit's review (under the highly deferential "substantial evidence" standard, *id.* at 1378-79) is in no way inconsistent with this Court's later decision in *KSR*.

2. Conversely, Bayer proposes (at 21) that the Federal Circuit managed to get one right in *Sanofi-Synthelabo* v. *Apotex, Inc.*, 550 F.3d 1075 (Fed. Cir. 2008), *cert. denied* 130 S. Ct. 493 (2009). The most salient difference between *Sanofi*, on the one hand, and *Pfizer*, *Longi*, and *Verlander*, on the other, seems to be that in *Sanofi*, the patentee won. In affirming the district court's bench-trial finding of validity, the *Sanofi* court repeatedly returned to the district court's findings of fact regarding "unexpected" results. See *id.* at 1086-90 (ultimately agreeing that a skilled person "would not have had the *expectation* that separating the enantiomers would be *likely*" to succeed) (emphasis added). The court also relied on the district court's conclusion that one aspect of the invention was "the paradigm of trial and error." *Id.* at 1088; compare Pet. App. 10a (decision below explaining that an invention is not obvious where prior art directed only "to vary all parameters or try each of

numerous possible choices until one possibly arrived at a successful result") (discussing *O'Farrell*). And the *Sanofi* court agreed with the district court that the facts presented were distinguishable from those in *Pfizer*, see 550 F.3d at 1089—which is a key point: these are fact-intensive cases.

3. Bayer also contends that, because *KSR* rejected "the overly exacting teaching-suggestion-motivation test," the Federal Circuit now applies an "improperly low second prong [reasonable expectation of success] in isolation." Pet. 29-30. As already shown, however, the Federal Circuit's "reasonable expectation of success" standard requires predictability; it is not "improperly low." Nor, contrary to the tenor of Bayer's argument, should there be any surprise if obviousness is more readily found after *KSR*—a case in which the obviousness standard was re-established as "expansive and flexible." 550 U.S. 415.[6]

In short, it is telling that, for Bayer, the bad cases—the problematic cases—are the ones where patents are invalidated. But different outcomes on different patents and different facts do not show a problem in the *legal standard*. That is particularly true where, as here, the Federal Circuit's faithfulness to the legal standard is confirmed by underlying factual determinations that are both amply supported and plainly dispositive of obviousness.

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[6] In addition, even after *KSR*, the Federal Circuit continues to recognize the importance of "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Takeda Chem. Indus., Ltd.* v. *Alphapharm Pty., Ltd.*, 492 F 3d 1350, 1356-57 (Fed. Cir. 2007) (quoting *KSR*, 550 U.S. at 418). The Federal Circuit does not apply a reasonable-expectations "prong" (Pet. 29) in isolation.

D. There is no circuit split.

Notwithstanding Bayer's dramatic declaration that "the decision below conflicts with the decisions of every other circuit that has addressed the issue" (Pet. 22), there is no circuit split over the question presented here. As discussed above, the court below required a showing of predictability. Accordingly, there is no conflict with courts outside the Federal Circuit that, according to Bayer, require the same thing.

Moreover, all the regional circuit cases cited by Bayer were decided between 1972 and 1983. See Pet. 23-25 & n.2. It is hardly fair to complain that "*no other circuit* employs the obviousness standard applied by the panel majority" (*id.* at 23) when no other circuit has decided an obviousness case since *KSR*. In fact, only one regional circuit decision has even cited *KSR*, and only in passing in a single case. See *Jennings* v. *Auto Meter Prods., Inc.*, 495 F.3d 466, 476 (7th Cir. 2007) (dismissing state law claims for lack of ripeness and noting that a pending patent application might be denied on obviousness grounds; describing *KSR* as "invalidating a patent as obvious and rejecting, as too lenient, the approach that the Federal Circuit has been taking to that issue").

In addition, all of Bayer's cases are older than the Federal Circuit itself, which was created to centralize patent decision-making. It is theoretically possible that a regional circuit court might be confronted with an obviousness issue at some point in the future. But with those circuits now some twenty-five years removed from having a body of obviousness law to call their own, there is no reason to think any of them would disagree with the Federal Circuit as to the proper application of *KSR* on similar facts. In short, there is no conflict for this Court to resolve.

E. Bayer's PTO-guidelines argument cuts *against* certiorari.

Further suggesting that Bayer's real problem is with *KSR*, and not the decision below, Bayer complains about PTO guidelines promulgated in the immediate wake of *KSR*—guidelines dated October 10, 2007 and titled, "Examination Guidelines for Determining Obviousness Under 35 U.S.C. 103 in View of the Supreme Court Decision in *KSR International Co. v. Teleflex Inc.*," 72 Fed. Reg. 57526. According to Bayer, these guidelines "point examiners to several recent Federal Circuit decisions that apply the same incorrect standard applied by the panel majority." Pet. 26 (citing 72 Fed. Reg. at 57532-33). The PTO's guidelines, however, correctly and expressly admonish examiners to consider predictability. In addition, the PTO is still digesting *KSR* and has even recently announced that it plans a guidelines revision. Even if uncertainty at the PTO were sufficient reason to grant certiorari (and it is not), the PTO does not need additional guidance from this Court at this time.

1. The PTO guidelines, which were issued two years *before* the decision below, cite a number of Federal Circuit decisions, including the *Pfizer* decision discussed above. Again, however, Bayer itself has recognized that *Pfizer* involved a patent that was held obvious because "the prior art 'predicted the results.'" Bayer Reply Br. at 28 (quoting *Pfizer* 480 F.3d at 1367). In addition, immediately before listing *Pfizer* as an example of obviousness, the guidelines instruct examiners that they may not issue an obviousness rejection without first resolving all *Graham* factual inquires, and articulating five findings. Included in those required findings: "that there had been a finite number of identified, predictable potential solutions to the recognized need or problem;" and

"that one of ordinary skill in the art could have pursued the known potential solutions with a reasonable expectation of success." 72 Fed. Reg. at 57532. The PTO has not "enshrined" any "improper standard" in its guidelines (Pet. 25-26); it has directed examiners to find predictability.

2. Moreover, as Bayer itself acknowledges, the PTO issued these guidelines *in response to KSR*. Pet. 26. Any criticism the office may have received from would-be patent holders about applying a less rigid obviousness standard (*ibid.*) is the result of *following KSR*, not departing from it.

The very blog post cited by the petition makes the point. In a post titled, "The Impact of *KSR*," the PTO director explained that *KSR* "was a landmark case," and "the Court's emphasis on a flexible approach clearly calls for new thinking about obviousness by patent examiners and practitioners alike." See http://www.uspto.gov/blog/ (Nov. 24, 2009) (cited in Pet. 26-27). The director noted, as Bayer does, that "[s]ome" have questioned the PTO's implementation of *KSR*. The director's response: "Because the Supreme Court clarified that teaching-suggestion-motivation was not the sole test of obviousness, the *Graham* analysis is not to be carried out in a rigid manner. As a result, *some claims that may have been found to be non-obvious before* KSR *will now correctly be found to be obvious.*" *Ibid.* (emphasis added).

3. Additionally, the director's blog post confirmed that further guidance from this Court would be premature at this time. The unnamed critics given voice by Bayer's petition apparently have asked the PTO to supplement its existing guidelines "to provide examples of non-obvious claims in view of *KSR*." *Ibid.* And the PTO plans to oblige: "Now that a body of case law has been decided in light of the *KSR* decision, we are

able to undertake that task. Office personnel are presently reviewing court decisions with an eye toward identifying factual scenarios to illustrate the developing law of obviousness." *Ibid.*

In short, certiorari should not be granted in this case based on criticism of how the PTO is implementing a decision of this Court that is less than three years old, particularly when the PTO itself is planning to issue additional guidance.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Respectfully submitted.

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